

Exhibit C

In The Matter Of:

In Re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation

Harry Johnson, M. D., FACOG, FACS

Vol. 1

March 21, 2017

Gore Brothers Reporting & Videoconferencing

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., MASTER FILE NO.
PELVIC REPAIR SYSTEM 2:12-MD-02327
PRODUCTS LIABILITY MDL 2327
LITIGATION JOSEPH R. GOODWIN
_____/ U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO ALL
WAVE 4 PLAINTIFFS and THESE
CASE-SPECIFIC PLAINTIFFS:

Mary Coppinger, et al.

vs.

Case No. 2:12-cv-05129

Ethicon, Inc., et al.
_____ /

TITLE PAGE CONTINUED ON NEXT PAGE.

1 The Telephonic deposition of HARRY JOHNSON,
2 JR., M.D., FACOG, FACS was held on Tuesday, March 21,
3 2017, commencing at 1:05 p.m., at Gore Brothers Reporting
4 & Videoconferencing, 20 South Charles Street, Suite 901,
5 Baltimore, Maryland 21022, before Susan M. Wootton,
6 Notary Public.

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21 REPORTED BY: Susan M. Wootton, RPR, CLR

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Deposition of HARRY JOHNSON

March 21, 2017

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(Exhibits attached to transcript.)

PROCEEDINGS

Whereupon,

HARRY JOHNSON, M.D., FACOG, FACS
called as a witness, having been first duly sworn to
tell the truth, the whole truth, and nothing but the
truth, was examined and testified as follows:

EXAMINATION BY MR. JONES:

Q Hi, Doctor. Could you state your full name
for the record, please?

A Harry Wallace Johnson, Junior.

Q My name is Nate Jones and do you understand
this, that I represent the plaintiffs in this
litigation, and this is my opportunity to ask you
questions related to the report that you have written
about the Prolift Mesh Kit?

A Yes.

Q Have you ever acted as a consultant
physician for Ethicon before, Doctor?

A I -- I have proctored some physicians on
Ethicon products.

Q When did you start proctoring physicians on

1 Ethicon products?

2 A I only did it probably for three, I don't
3 know, three or four physicians somewhere around the
4 year 2000.

5 Q What products, what Ethicon products did
6 you proctor other physicians on?

7 A TVT.

8 Q Is it fair to say you've never proctored
9 other physicians on the Prolift Mesh Kit for Ethicon
10 before?

11 A I -- I've been an instructor in a cadaver
12 course where I instructed on Prolift.

13 Q Any other work? Were you paid by Ethicon
14 for that work?

15 A I believe that work was done for a company
16 called Innovations in Medical Education and Technology.

17 Q Fair to say that Ethicon has never asked
18 you to perform consulting work on the Prolift Mesh Kit
19 device, outside of litigation?

20 A Right. I'm not a consultant on that
21 product.

1 Q When did you -- well, let me ask you this
2 first. How many times have you used the Prolift Mesh
3 Kit device?

4 A Approximately 150 times.

5 Q When did you start using the device?

6 A Mid 2000. So, you know, 2005, 2006,
7 somewhere in there. I'm not even sure of the exact
8 year.

9 Q Doctor, as part of your review of
10 materials, in forming your opinions related to the
11 Prolift Mesh Kit device, have you reviewed what are
12 commonly referred to as society statements on
13 Transvaginal Mesh for the Repair of Pelvic Organ
14 Prolapse?

15 A I have.

16 Q Why did you first use the Prolift measure
17 device, Doctor?

18 A It was a surgical procedure, that was less
19 invasive than an abdominal procedure, that was designed
20 to give you a result that was better than a native
21 tissue vaginal procedure.

1 Q And I assume at some point in time you
2 stopped using the Prolift Mesh Kit device, is that
3 fair?

4 A I did.

5 Q Why did you stop using it?

6 A Because I couldn't obtain it at my hospital
7 any longer.

8 Q When? What time period was that?

9 A I'm not sure of the exact year. I would
10 guess somewhere around 2010 or '11, somewhere in there.
11 I don't know the exact year.

12 Q At some point in 2010 or 2011, your
13 hospital stopped purchasing the Prolift Mesh Kit
14 Device?

15 A Yes.

16 Q And at that point in time, you stopped
17 using the Prolift Mesh Kit Device because your hospital
18 no longer made it available to you, fair?

19 A Yes.

20 Q What hospital was that?

21 A University of Maryland Medical System.

1 Q Did you have any conversations with any of
2 the physicians, at that point in time, about the
3 hospital's no longer making the Prolift Mesh Kit Device
4 available for use?

5 A I don't believe so.

6 Q You didn't make any effort to persuade the
7 hospital to continue to purchase the Prolift Mesh Kit
8 Device, at that point in time?

9 A Well, I let them know that I was satisfied
10 with the device.

11 Q Could you repeat that? Sorry, sometimes
12 things get lost over here.

13 A I let them know that I was satisfied with
14 the device.

15 Q And what was their response?

16 A That they couldn't obtain it from, from
17 Ethicon any longer.

18 Q Were there any other physicians at the
19 University of Maryland Hospital that were, at that
20 point in time, using the Prolift Mesh Kit Device?

21 A No.

1 Q Fair to say that in 2010 or 2011, you were
2 the only physician at the University of Maryland
3 Hospital using the Prolift Mesh Kit Device?

4 A Yes.

5 Q Doctor, did you prepare a reliance list
6 associated with your report in this case or this
7 litigation?

8 A I have a list of -- of materials, yes.

9 Q And did you prepare that list?

10 A That was a list -- well, the materials, the
11 materials that I obtained were from Butler Snow and
12 they prepared the list.

13 Q Was it important for you, Doctor, in
14 forming your opinions in this litigation related to the
15 Prolift Mesh Kit Device, to review internal Ethicon
16 company documents about the Prolift Mesh Kit Device?

17 A I didn't review internal Ethicon memos
18 regarding the device.

19 Q Doctor, how long did it take you to
20 draft -- well, let me back up.

21 Did you bring with you today any materials,

1 Doctor?

2 A I brought some articles, my CV, my report.

3 Q If we could -- go ahead.

4 A Like, there are some review articles and
5 then some IFU and educational material from Ethicon for
6 physicians.

7 MR. COMBS: And Nate, this is Phil Combs.
8 I brought a flashdrive that has a copy, an electronic
9 copy of the materials on Dr. Johnson's reliance list.

10 MR. JONES: Why don't we do it like this.
11 Let's mark the flashdrive as Exhibit 1 for the record.
12 And Phil, is there a password for that flashdrive?

13 MR. COMBS: Nate, there probably is.
14 Honestly, I don't know it. I can get it for you.

15 MR. JONES: Yeah, that's fine.

16 MR. COMBS: Okay. Give me one second just
17 to make a note of that so I don't forget that. All
18 right. I'm good now.

19 (Johnson Exhibit 1 was marked for purposes
20 of identification.)

21 MR. JONES: And then if we could mark the

1 materials that the doctor has brought as Exhibit 2.

2 THE REPORTER: Do you want the entire
3 folder marked?

4 MR. COMBS: Yeah, Nate, it's a three-ring
5 binder.

6 THE REPORTER: Do you want this on the
7 record?

8 MR. COMBS: Yeah, we can stay on the
9 record.

10 THE REPORTER: Okay.

11 MR. COMBS: Could I make a suggestion on
12 that, Nate? We have an Index or a Table of Contents
13 that's just one page that lists everything that's on
14 it.

15 There's not a single thing on it that --
16 that you're not -- that you don't have.

17 It's basically four sections. It just has
18 his general report, some literature, FDA notifications,
19 and the IFUs.

20 And could we just maybe mark the Table of
21 Contents, so that we don't have a 2000 page exhibit?

1 MR. JONES: Yeah, that's fine, but I do
2 want to mark his report.

3 MR. COMBS: Okay.

4 MR. JONES: So let's mark the Table of
5 Contents, and again it's hard for me, because I'm not
6 there.

7 But I'll trust your report of what's in
8 front of him. And it sounds like we already have that
9 stuff.

10 MR. COMBS: Yes.

11 MR. JONES: I do want to mark the report.
12 So we'll mark the Table of Contents as Exhibit 2 and
13 we'll mark his Expert Report as Exhibit 3.

14 MR. COMBS: Okay. That is fine. Those
15 have been handed to the court reporter.

16 MR. JONES: Thanks, Phil.

17 THE REPORTER: Just give me one second, and
18 I'll mark everything here.

19 (Johnson Exhibits 2 and 3 were marked for
20 purposes of identification.)
21

1 THE REPORTER: Okay, they're marked.

2 Q Thank you. Doctor, do you know what year
3 Prolift was launched by Ethicon?

4 A I think it was around 2005. That's an
5 estimate.

6 Q Did you review, in forming your opinions in
7 this case, the application that Ethicon filed with the
8 FDA?

9 Let's refer to it as the 510(k)
10 Application, to market the Prolift Mesh Kit Device?

11 A I did not.

12 Q Fair to say since you didn't review it, you
13 don't know when that application was filed?

14 A That's correct.

15 Q Do you know anything about the regulatory
16 history concerning the Prolift Mesh Kit Device, as it
17 relates to it being cleared by the FDA for market?

18 A I know it was cleared by the FDA.

19 Q Other than that, any other information?

20 A I don't believe so.

21 Q Doctor, from the time period of the

1 mid 2000s, when you first started using the Prolift
2 Mesh Kit Device, to 2010 or '11 when you stopped using
3 the Prolift Mesh Kit Device, were there any other
4 physicians besides yourself at the University of
5 Maryland Hospital also using the Prolift Mesh Kit
6 Device?

7 A Well, first I'll say; you know, I know
8 those years are just estimates. I don't know the -- I
9 would have to check the exact years.

10 But during that time, I was training
11 fellows in urogynecology, that worked with me for up to
12 a year, that -- that I trained to use the device.

13 But there were no other attending
14 physicians there using the device.

15 Q Other than the Prolift Mesh Kit Device, did
16 you use any other transvaginal mesh kits for the repair
17 of pelvic organ prolapse?

18 MR. COMBS: Object to form.

19 THE WITNESS: I've used the AMS device and
20 that's the only one that I can recall.

21 Q Do you recall what AMS device you used?

1 A I don't. I don't. I can't recall the name
2 of it, but it was a posterior wall repair.

3 Q And why did you use that device, Doctor?

4 A I was at another hospital in the system and
5 that was the device that they had.

6 Q Have you -- we talked a little bit about
7 your use of the Prolift Mesh Kit Device, and now I want
8 to a break it up and ask you specifically about the
9 different types of repair kits for the Prolift Mesh Kit
10 device.

11 Have you used the Prolift posterior mesh
12 kit?

13 A I have.

14 Q Have you used the Prolift anterior mesh
15 kit?

16 A I have.

17 Q And have you used the Prolift total mesh
18 kit?

19 A I have.

20 Q And correct me if I'm wrong, but I think
21 you said you've used the Prolift about 150 times, fair?

1 A Approximately, yes.

2 Q Okay. Of those 150 times, how many times,
3 can you give me a breakdown of how many times were for
4 posterior kit, anterior kit and Prolift total?

5 A I can't, off the top of my head, give you
6 that number; but I would estimate that I used the
7 anterior more than the total or the posterior.

8 Q You can't give me an exact number, but more
9 likely than not, your use of the Prolift mesh kits
10 would have been predominantly the use of the Prolift
11 anterior mesh kit, is that fair?

12 A It would be, yeah, anterior, greater than
13 posterior, greater than total, would be my estimate.

14 Q And is there a reason for that, Doctor?

15 A It just was the procedure that was needed
16 by the patient that I was seeing.

17 Q Did you ever have any concerns about using
18 transvaginal mesh for the repair of -- or let me -- let
19 me strike that.

20 Did you ever have any concerns about using
21 transvaginal mesh in a posterior repair?

1 A Not really.

2 Q Do you currently use any transvaginal mesh
3 for the repair of pelvic organ prolapse, Doctor?

4 A No. Well, I mean, other than for
5 mid-urethral slings.

6 Q Yeah, and I'm just asking about pelvic
7 organ prolapse.

8 A Okay. No, I don't.

9 Q Why is that, Doctor?

10 A Well, there's not really very much
11 available.

12 Q There are products that involve the use of
13 transvaginal mesh to treat pelvic organ prolapse
14 currently available, correct?

15 THE REPORTER: I'm sorry, can you repeat
16 the question? You faded out a little bit.

17 MR. JONES: Yeah. Doctor, you do know that
18 there are products currently available that involve the
19 use of transvaginal mesh to treat pelvic organ
20 prolapse, correct?

21 THE WITNESS: Yes.

1 Q Okay. You don't currently use any of those
2 products, correct?

3 A Correct.

4 Q Other than your use of mesh to treat stress
5 urinary incontinence, do you use any mesh whatsoever in
6 your clinical practice?

7 A I do.

8 Q Can you describe that for me?

9 A I use -- I use abdominal mesh to perform
10 sacral colpopexy for pelvic organ prolapse.

11 Q Which mesh product do you use for that
12 repair?

13 A Primarily now I use the Coloplast mesh, but
14 I also use the Prolene soft mesh.

15 Q Why do you currently primarily use the
16 Coloplast mesh?

17 A Well, at the -- at my main hospital, that's
18 what we have.

19 Q Have you noticed the difference between the
20 handling characteristics of the Coloplast mesh as it
21 compares to the Prolene soft mesh?

1 A No.

2 Q Do you know if there's a difference in the
3 density or weight between the Coloplast mesh and the
4 Prolene soft mesh that you use?

5 A There is some difference in the weight.

6 Q Okay.

7 A I would have to check the density.

8 Q What's the difference in the weight?

9 A Coloplast, I believe is a little less,
10 although I don't have the exact numbers.

11 Q Is there a difference in the pore size
12 between those two meshes?

13 A Yes.

14 Q Okay. What's the difference?

15 A I would have to check that number. I mean,
16 I know they're both large pore meshes.

17 Q Do you know which of those two meshes has
18 larger sized pores?

19 A I believe the Coloplast does.

20 Q Is there a difference?

21 A I'd have to, again, I'd have to check the

1 exact number.

2 Q Sure. Is there a difference in the
3 stiffness of the two meshes?

4 A Well, handling them as a surgeon, I find
5 them to be very comparable in stiffness.

6 Q Do you know if there's been any studies
7 published that compare the stiffness between the
8 Coloplast mesh and the Prolene soft mesh?

9 A I know I've seen, I've seen charts that
10 compare the two, but I can't give you the exact numbers
11 comparing the two.

12 Q Doctor, do you know who Gene Kammorer is,
13 as it relates to this litigation?

14 A No.

15 Q Doctor, do you know who Charlotte Owens is,
16 as it relates to this litigation?

17 A No.

18 Q Doctor, do you know who Martin Wylesburg
19 is, as it relates to this litigation?

20 A No.

21 Q Doctor, do you know who Piet Hinoul is, as

1 it relates to this litigation?

2 A No.

3 Q Doctor, do you know who Laura Angellini is,
4 as it relates to this litigation?

5 A No.

6 MR. JONES: Are you there? Hello.

7 MR. COMBS: We can hear you, Nate.

8 Q Okay. Doctor, do you know who Dr. Kimberly
9 Kenton is?

10 A I know who that is.

11 Q Did you review her deposition in forming
12 your opinions in this case?

13 A No, I did not.

14 Q Do you know who Dr. Juan Felix is?

15 A No.

16 Q Okay. Do you know who a Dr. Roger McLendon
17 is?

18 A No.

19 Q Do you know who a Dr. Anne -- or excuse
20 me -- do you know who Anne Wilson is, as it relates to
21 this litigation?

1 A No.

2 Q All right. Doctor, let's talk about your
3 use of Prolene soft, outside of the Prolift mesh kit
4 device, and we're going to talk about the
5 transabdominal approach here.

6 How many times have you used Prolene soft
7 through the abdomen to treat pelvic organ prolapse?

8 A I would estimate in excess of -- I would
9 estimate in excess of 700 cases.

10 Q When did you start using Gynemesh PS
11 through the abdominal approach?

12 A I -- I can't remember the exact year, but I
13 started using Prolene soft mesh sometime after -- I
14 don't know -- I would estimate 1998 or something like
15 that.

16 Q Since your use in 1998 until today of using
17 Gynemesh PS through the abdominal approach, has there
18 been any fluctuation in your use of Gynemesh PS,
19 meaning, have there been times when you've used it more
20 than other time periods from 1998 to today?

21 MR. COMBS: Object to form.

1 A Well, the Prolene soft mesh is the only
2 mesh that I was using through the abdomen until, you
3 know, until the hospital switched to the Coloplast
4 mesh.

5 Q When did your hospital switch to the
6 Coloplast mesh?

7 A Probably, I would guess maybe three years
8 ago, something like that.

9 Q So, fair to say as of three years ago, your
10 use of Gynemesh PS through the abdominal approach
11 decreased, correct?

12 A Yes.

13 Q And it decreased because the hospital
14 started purchasing Coloplast mesh, correct?

15 A That's correct.

16 Q Do you know why your hospital started to
17 purchase Coloplast mesh?

18 A Well, the meshes were comparable and the,
19 the pricing was better for Coloplast.

20 Q When you say the meshes are comparable, are
21 you saying that the two meshes are comparable in their

1 clinical outcomes?

2 A Well, the decision was on the
3 characteristics of the mesh. So it was a type 1 mesh
4 with large pores, low weight, monofilament.

5 Q Have you noticed any clinical -- well, let
6 me strike that.

7 Have you noticed any differences in the
8 clinical outcomes in your patients that you've
9 implanted the Gynemesh PS mesh abdominally in, as
10 compared to the Coloplast mesh?

11 A I have not.

12 Q Doctor, do you keep a patient registry of
13 your mesh patients?

14 MR. COMBS: Object to form.

15 THE WITNESS: There's a registry of
16 minimally invasive cases, which is primarily the
17 slings, that's done through --

18 Well, it's a center -- we're a center of
19 minimally invasive gynecologic surgery, and there's a
20 national registry.

21 I'm blanking on the name of it, but I

1 believe that mostly would look at cases like slings.

2 Q Sure.

3 A I don't think -- I don't think that it
4 looks at open abdominal cases, because they're not
5 minimally invasive.

6 Q Okay. So let me break that down a little
7 bit. It's fair to say that you don't have a patient
8 registry that tracks your patients who have had a
9 transvaginal mesh product implanted for the use of
10 pelvic organ prolapse, fair?

11 A Well, I do have a registry. I just don't
12 implant mesh vaginally, currently.

13 Q All right. Let me back up. You don't have
14 a patient registry that tracks the performance of your
15 patients, when you use mesh through the abdomen to
16 treat pelvic organ prolapse, correct?

17 A Correct.

18 Q And --

19 A Unless -- unless it's -- I'm not sure that
20 they -- I have to check if the registry keeps track of
21 robotics and laparoscopy, but I don't have it for open

1 cases.

2 Q And because you currently don't use
3 transvaginal mesh for the treatment of pelvic organ
4 prolapse, you don't have a patient registry for that,
5 correct?

6 A Well, no, I have a registry. I just don't
7 have cases that are going into it, currently.

8 Q How many patients are in that registry?

9 MR. COMBS: Object to form.

10 THE WITNESS: That's a -- it's a national
11 database, so I really don't know.

12 Q Okay. Do you have access to that database?

13 A Well, I'm part of it, so I believe I do.

14 Q Okay. And what's the name of that
15 database?

16 A I -- I don't -- I don't have the name with
17 me today. I would have to get that for you.

18 Q Okay.

19 A It's through -- it's through the center,
20 The Center for Minimally Invasive Gynecology at
21 Maryland with the -- I believe the name of the company

1 is SRC or Surgical Review. I would have to check the
2 name for you.

3 Q Okay. But that -- would that be a case of
4 registry that we could, or that you could access and
5 pull out information, say, that would report the
6 erosion rate of the patients in which you've implanted
7 the Prolift Mesh Kit devices?

8 A I believe that that -- I believe that that
9 database is for --

10 Well, it's for complications related to
11 surgery. But it's through the hospital, so I'm not
12 sure that they have access to the outpatient chart.

13 So I don't actually do the entry into that
14 database. It's independent of the surgeons.

15 Q Okay.

16 A So I would have to check that.

17 Q Okay. Would it have information related to
18 the recurrence rate in those patients? Recurrence
19 meaning the pelvic organ prolapse that was treated with
20 the mesh recurring?

21 A I would have to check that.

1 Q Okay. It's fair to say that that's not
2 information that you pulled and relied on, in forming
3 your opinions in this -- in your report?

4 A That's correct.

5 Q Doctor, have you ever used the Prolift plus
6 mesh kit?

7 A I do not recall using that.

8 Q Doctor, do you know who Axel Arnaud is, in
9 relationship to this litigation?

10 A I do not.

11 Q Doctor, are you familiar with the medical
12 diagnosis of chronic mesh pain syndrome?

13 A I'm familiar with chronic pain syndrome.

14 Q Yeah, I'm asking specifically about a term,
15 quote, chronic mesh pain syndrome. Have you heard of
16 that diagnosis?

17 A I've heard of that.

18 Q Okay. What's your understanding of that,
19 that diagnosis, quote, chronic mesh pain syndrome?

20 A Chronic pain in a patient who has mesh
21 placed or implanted.

1 Q Have you seen that in your own practice,
2 Doctor?

3 A I've seen patients who had pain that have
4 had mesh procedures.

5 Q Do you believe that the presence of the
6 Gynemesh PS mesh, inside of a woman's body, can cause
7 that woman pain?

8 A I believe that patients who have had
9 surgical procedures formed -- performed, which include
10 mesh placement, and include operations without mesh
11 placement, can have pain after the surgery is
12 performed.

13 Q Do you believe the mesh itself can cause
14 pain in -- to a woman?

15 A I believe it's related to the surgical
16 procedure, and it can be found in patients with mesh as
17 well as patients without mesh.

18 Q Fair to say that you do not believe the
19 mere presence of polypropylene mesh inside of a woman's
20 vagina can cause her pain, fair?

21 MR. COMBS: Object to form.

1 THE WITNESS: I don't believe the mere --
2 mere presence of mesh is a cause of all pelvic pain. I
3 think it's related to the procedure that the patient
4 had, and that may or may not include mesh.

5 Q Okay. And when a surgeon like yourself
6 implants the Prolift Mesh Kit device in a patient that
7 follows the instructions for use, is there any reason
8 why, based on your expert opinion, why the mesh, say
9 five years after the date of implant, will have excess
10 tension on the mesh?

11 A I'm not completely sure what you mean by
12 that.

13 Q Sure. You implant a mesh, Prolift Mesh Kit
14 device. Say it's a posterior mesh kit. You follow the
15 instructions for use. The surgery goes well.

16 Five years after you put it in, the lady
17 comes back and sees you and you examine her and there's
18 tension on the mesh arms.

19 Can you explain why -- well, first off, has
20 that ever happened in your practice?

21 A Well, I -- I have no way to measure tension

1 on mesh arms in the vagina.

2 Q Have you ever examined a patient where
3 they've had tightness around the transvaginal mesh
4 device?

5 A Well, the -- the placement of the
6 transvaginal mesh device is an operation in the vagina
7 like any operation in the vagina.

8 And when you do that, you can have scarring
9 of the vagina with mesh or without mesh, that can
10 reduce the caliber of the vagina.

11 Q Have you ever examined a patient where
12 there's been -- where you have noted tension on the
13 Prolift mesh arms?

14 A Again, I don't -- I don't know how you
15 would measure tension in the vagina.

16 Q Have you ever removed transvaginal mesh
17 from women, Doctor?

18 A I have.

19 Q How many removal surgeries have you
20 performed?

21 MR. COMBS: So Nate, you're talking about

1 now for meshes implanted for pelvic organ prolapse?

2 MR. JONES: Well, let me ask about all of
3 it. So I'll get to it, Phil, but Doctor, why don't you
4 give us a breakdown of the mesh, total mesh removal
5 surgeries you've performed.

6 MR. COMBS: Object to form.

7 THE WITNESS: Total mesh removals would
8 probably be, approximately, this is an estimate, around
9 110 or so.

10 Q And those mesh removal surgeries that you
11 estimate at around 110 or so, do those include mesh
12 revision surgeries?

13 A That would include patients taken to the
14 operating room for revision or removal of mesh.

15 Q Okay. How many surgeries to revise mesh,
16 outside of the operating room, have you performed?

17 A That -- that number would be very low,
18 probably, I don't know. Maybe 10 to 15, not many.

19 Q So the vast majority of the mesh removal or
20 revision surgeries you have performed have been in the
21 operating room, correct?

1 A Yes.

2 Q And of those 120 to 125 mesh removal or
3 revision surgeries that you've performed, how many of
4 those have been related to pelvic organ prolapse mesh?

5 MR. COMBS: Object to form.

6 A I would estimate at approximately 35 or so.

7 Q And the remaining number would be related
8 to mesh used to treat stress urinary incontinence?

9 A That's correct.

10 Q When did you start performing mesh removal
11 or revision surgeries, Doctor?

12 A Early to mid 2000s.

13 Q When is the last time you performed a mesh
14 removal or revision surgery?

15 A For pelvic organ prolapse?

16 Q For either.

17 A For stress urinary incontinence; today.

18 Q Tell me about the revision surgery you
19 performed today.

20 A It was a -- a patient who had a TVT-O
21 performed approximately 11 years ago that has recurrent

1 stress incontinence and I revised her sling today.

2 Q Did you implant that patient with a
3 additional transvaginal mesh product?

4 A Well, I removed the TVT-O and implanted a
5 TVT.

6 Q Besides recurrence of stress urinary
7 incontinence, were there any other symptomatology that
8 led you to remove her TVT-O mesh?

9 A No.

10 Q And you know that the Gynemesh PS mesh is
11 made from the same polypropylene material that is in
12 the TVT line of products, correct?

13 A Yes.

14 Q Doctor, do you know what standards a
15 medical device company like Ethicon applies when
16 drafting the instructions for use associated with a
17 product like Prolift?

18 A I've never drafted an IFU, so I'm not, I'm
19 not an expert on the standards required.

20 Q Doctor, are you familiar with what's
21 referred to as the TVM Group, as it relates to the

1 Prolift Mesh Kit device?

2 A I am.

3 Q Doctor, are you aware that members of the
4 TVM Group reported to Ethicon that the Gynemesh PS
5 mesh, when used transvaginally, would shrink inside of
6 women's vaginas at three months after implant?

7 MR. COMBS: Object to form.

8 THE WITNESS: Well, I am. I would
9 expect -- I would expect that because of scarring of
10 the tissue where it's placed.

11 In normal healing, you get scarring and
12 shrinkage of tissue.

13 Q Doctor, how is the Prolift Mesh Kit device
14 held in place or fixated inside of a woman's vagina?

15 A Which, which device are you talking about?

16 Q Start with the Total.

17 A Well, the Total has three arms on each side
18 that are placed posteriorly through the sacrospinous
19 ligament, and anteriorly through the arcus tendineus
20 fasciae pelvis, which are structures lateral to the
21 vagina.

1 And then you can use an anchoring suture at
2 the apex, if you feel like you need to.

3 Q Doctor, are you familiar with the Committee
4 Opinion 513 which is a joint opinion from the medical
5 societies of ACOG and OGS, as its relates to
6 transvaginal mesh for the treatment of pelvic organ
7 prolapse?

8 A Yes.

9 Q And what is the significance of that
10 Committee Opinion 513, in forming your opinions in this
11 litigation?

12 A That was one of the pieces of information
13 that, that I reviewed in forming my opinions.

14 Q Do you agree or disagree? Well, first off,
15 what was the finding in Committee Opinion 513 from ACOG
16 and OGS?

17 MR. COMBS: Object to form.

18 THE WITNESS: Well, it's a five-page report
19 discussing synthetic, synthetic mesh and the use for
20 pelvic organ prolapse.

21 Q Are there any statements in that five-page

1 report that you disagreed with?

2 A Well, I don't think I agree with everything
3 in this statement.

4 Q Okay. Tell me what -- tell me the -- what
5 you disagreed with in that statement?

6 A Well, I would have to read this entire
7 statement to -- to agree with you that I don't agree
8 with everything in this statement.

9 Q All right. Let's save -- let's save each
10 other both some time here and I'll just ask you:

11 Do you -- a portion of the Committee
12 Opinion states that mesh kits should only be used in
13 high-risk individuals for which no other options are
14 available or appropriate.

15 Do you agree with that finding or opinion
16 contained in this joint opinion from ACOG and OGS?

17 A Well, I -- I would agree that you should
18 have used the mesh in appropriate patients, as an
19 alternative to abdominal placement of mesh, and that
20 each patient has to be evaluated individually to, to
21 decide whether placement of that mesh is appropriate in

1 their particular case or not.

2 Q Doctor, have you attended the OGS
3 conventions?

4 A I have from time to time.

5 Q In OGS conventions, are there
6 representatives from medical device companies?

7 A There's usually a area of exhibits from
8 companies. It's not actually in the meeting, but it's
9 adjacent to it.

10 Q Okay. As you sit here today, do you recall
11 a report from a medical society stating that the use of
12 transvaginal mesh for the repair of pelvic organ
13 prolapse was an experimental treatment?

14 A No.

15 Q As you sit here today, do you recall a body
16 of literature out of the University of Pittsburgh, led
17 by Dr. Pam Moalli studying meshes used for pelvic organ
18 prolapse repair?

19 A I have seen the studies by Dr. Moalli.

20 Q Okay. And generally, and this isn't a
21 memorization test, but generally what do those studies

1 discuss?

2 MR. COMBS: Object to form.

3 THE WITNESS: The -- the ones that I'm
4 familiar with looked at different characteristics of
5 the mesh, different physical characteristics of -- of
6 meshes from different companies.

7 Q And do you generally recall any of the --
8 the findings or conclusions that Dr. Moalli and her
9 group of researchers made about mesh characteristics,
10 as -- as it relates to transvaginal mesh for pelvic
11 organ prolapse?

12 A It's been a while since I looked at those
13 studies. I would have to look at them.

14 Q Okay. Doctor, you are aware that of the
15 mesh products currently on the market used through the
16 abdominal approach to treat pelvic organ prolapse, that
17 Gynemesh PS is one of the most stiff meshes available
18 for physicians to use?

19 MR. COMBS: Object to form.

20 THE WITNESS: I mean, in my experience, I
21 find it very pliable as I hold it in my hands. The --

1 the -- the numbers with that, I -- I can't give you
2 right off the top of my head.

3 Q Doctor, have you reviewed any of the
4 522 orders from the FDA as it relates to Gynemesh PS?

5 A I have not.

6 Q Doctor, as we sit here today, do you know
7 the specific pore size of the Gynemesh PS mesh?

8 A I believe it's 2400 microns.

9 Q Do you know the specific weight of the
10 Gynemesh PS mesh?

11 A 42.5.

12 Q And do you know the pore size of the
13 Gynemesh PS mesh? Well, let me ask you this way.

14 You know that the pore size of the
15 Gynemesh PS mesh gets smaller after it's implanted
16 inside the woman's vagina, correct?

17 MR. COMBS: Object to form.

18 THE WITNESS: Well, I know -- I know it's
19 possible it could get smaller, but it's -- you know, to
20 be a macroporous mesh it needs to be greater than 75
21 and this is 2400.

1 Q Got it. But you do know that the pore size
2 becomes smaller over time, after it's implanted inside
3 the body, correct?

4 A I don't know that for sure.

5 Q Okay. Have you ever read any peer-reviewed
6 medical literature discussing how the pore size of the
7 Gynemesh PS mesh, or other meshes implanted inside a
8 woman's vagina, gets smaller after it's implanted?

9 MR. COMBS: Object to form.

10 THE WITNESS: I'm sure I've read that, but
11 I don't recall it specifically.

12 MR. JONES: Okay. Why don't we take a
13 quick break. I'm going to review my notes. I might
14 not have much left to go. Take about a 5 or 10 minute
15 break.

16 THE WITNESS: Okay.

17 MR. COMBS: Okay. Nate, are we going to
18 leave the line open or do you want to call back in?

19 MR. JONES: No, we'll leave the line open.
20 Do you guys want to take a longer break?

21 MR. COMBS: It doesn't matter. It's two,

1 it's 2:12. When do you want us to be back here ready
2 for more questions?

3 MR. JONES: Let's be back at 2:30, and then
4 I probably don't have much left.

5 I might have 30 more minutes, maybe an hour
6 on at most, but probably about 30 more minutes after
7 that.

8 MR. COMBS: Okay. I mean, you can't have
9 an hour, but --

10 MR. JONES: How much total time do I have;
11 two hours?

12 MR. COMBS: Yeah.

13 MR. JONES: Okay. Let me review my notes.
14 We'll come back at 2:30.

15 MR. COMBS: Let's come back at, let's come
16 back at, let's come back at 2:20.

17 And the only reason -- I'm not trying to
18 pressure you at all, I just -- I have a flight I want
19 to make sure I catch.

20 MR. JONES: Oh, Phil, yeah. I'm not trying
21 to be like that. So let's come back at 2:20. I

1 guarantee you I -- I don't have much time left so.

2 MR. COMBS: Okay. Great. And if you need,
3 more time -- oh, I'm sorry, Nate. I kind of didn't
4 realize what time it was. It's 2:13. How about we
5 come back at 2:25?

6 MR. JONES: Got it. Perfect.

7 MR. COMBS: I spaced on what time it was
8 when I said come back at 2:20. Sorry.

9 MR. JONES: You're fine.

10 (A short break was taken.)

11 MR. JONES: Doctor, are you ready after a
12 short break?

13 A Yes.

14 Q Okay. I'm going to ask you whether you
15 agree or disagree with this statement:

16 The published literature reveals that while
17 vaginal POP repair with mesh often restores anatomy --

18 THE REPORTER: I'm sorry, can you say that
19 question again, because it faded out in the beginning?

20 MR. JONES: Yes. Doctor, I'm going to ask
21 you simply whether you disagree or agree with this

1 statement:

2 The published literature reveals that while
3 vaginal POP repair with mesh often restores anatomy, it
4 has not been shown to improve clinical benefit over
5 traditional non-mesh repair. This is particularly true
6 for apical and posterior repair with mesh.

7 Do you agree or disagree with that
8 statement?

9 A I don't completely agree with that
10 statement.

11 MR. JONES: Those are all questions that I
12 have for you, Doctor, at this point. I might have some
13 follow-up questions in relationship to questions Phil
14 has for you, if he has some.

15 But those are all the questions that I have
16 for you for now, and thank you very much for your time,
17 Doctor.

18 (A discussion was held off the record.)

19 EXAMINATION BY MR. COMBS:

20 Q All right. Dr. Johnson, my name is Phil
21 Combs. I want to ask you some questions now on behalf

1 of Ethicon.

2 During your direct examination, do you
3 remember when Mr. Jones asked you some questions about
4 mesh removals?

5 A Yes.

6 Q And I just want to ask you a couple of
7 follow-up questions on that.

8 You testified that you had done
9 approximately 115 to 125 mesh removals total, do you
10 remember that?

11 A Yes.

12 Q Would those have been your cases?

13 A They were -- those patients were referred
14 to me with mesh problems.

15 Q And what kind of referral practice do you
16 have?

17 A I have a tertiary referral type practice at
18 the University of Maryland. I see patients from
19 approximately a -- generally a five-state region.

20 Q So, in regard to the testimony that you
21 gave to Mr. Jones, those removals, there would be no

1 denominator for the amount of meshes that had been put
2 in by the implanting physicians, would there?

3 A Right. Those -- those were not my
4 patients. The majority were not my patients.

5 Q All right. So the second line of questions
6 I want to ask you about is, Mr. Jones asked you about
7 the drafting of IFUs. Do you remember those questions?

8 A Yes.

9 Q You testified that you were not a
10 regulatory person and were not an expert on the
11 standards required to draft an IFU, is that correct?

12 A That's correct.

13 Q Now, do you, in fact, have knowledge about
14 the knowledge of surgeons regarding potential
15 complications?

16 A Yes.

17 Q How is it that you would have that
18 knowledge?

19 A Well, I -- I have knowledge of surgical
20 complications through my training and experience.

21 So that includes medical school, residency,

1 fellowship training, 30 years of experience, a review
2 of medical literature, attending conferences, basically
3 anything that, that involves surgical practice and
4 education.

5 Q And would you also have information
6 regarding the complications related to vaginal surgery
7 that are known by other physicians?

8 A Yes.

9 MR. JONES: Objection.

10 MR. COMBS: Do you, in fact, teach other
11 physicians vaginal surgery?

12 A I do.

13 Q And could you just explain what that
14 encompasses?

15 A Well, I've -- I've trained medical people
16 on all different levels, which includes medical
17 students, residents and fellows, as well as other
18 surgeons, regarding the performance of vaginal
19 procedures.

20 And that can include basically any
21 procedure that's done through the vagina that doesn't

1 involve, in general, cancer, unless it's an early, an
2 early stage or something that's unexpected.

3 That involves treatment of anterior and
4 posterior walls of the vagina, hysterectomy, other
5 things that can happen to the vagina, uterus, bladder,
6 rectum and urethra.

7 Q And during what time period have you been
8 educating medical students, residents, fellows and
9 fellow surgeons?

10 A Well, I started my residency in 1985, and
11 during residency programs, you teach other residents,
12 residents that are below, you as well as medical
13 students.

14 And then I became an attending physician in
15 1989, and since that time, I've been involved in
16 teaching residents, medical students and fellows.

17 I was head of the residency training
18 program at the University of Maryland from nineteen,
19 approximately 1993 to 2000; basically 2004, basically
20 about 10 or 11 years.

21 I trained fellows in urogynecology for

1 approximately 25 years, which meant that I had one
2 fellow per year that spent time with me.

3 And then I've acted as a consultant to
4 physicians in the Baltimore region providing them a
5 referral source as well as instructing them on
6 procedures if they so inquire.

7 Q Is there any way you can estimate for us
8 the number of surgeons that you have trained?

9 A Well, I've had six residents a year since
10 approximately 1989.

11 The first three years, there was only four
12 residents per year because I was at the National Naval
13 Medical Center and they only have four.

14 Maryland has six per year and for the last
15 three years, we had seven per year and that would be
16 over the course of 18 years for residents.

17 And then I've trained approximately
18 20 fellows in urogynecology, pelvic reconstructive
19 surgery.

20 MR. COMBS: Dr. Johnson, that's all the
21 questions I have at this time. Thank you. Nate?

1 EXAMINATION BY MR. JONES:

2 Q Yeah, just a couple. Doctor, you talked
3 about the 115 to 125 mesh removal or revision surgeries
4 that you have performed.

5 Those were predominantly referrals for mesh
6 related problems, correct?

7 A Yes.

8 Q What mesh problems would you commonly see
9 in these referrals that were sent to you?

10 A Most commonly would be an erosion. I also
11 saw some patients with pain.

12 MR. JONES: Those are all the questions
13 that I have. Thanks, Doctor. Thanks, Phil.

14 MR. COMBS: Thank you. Dr. Johnson will
15 read and sign.

16 THE REPORTER: Okay. And Mr. Jones, what
17 would you like to receive, and do you have any rush?

18 MR. JONES: No rush. And let me check with
19 my -- the people that tell me what to do and send me an
20 E-Mail. I can reply back very promptly and let you
21 know exactly what we need.

1 THE REPORTER: Okay. That would be great.

2 MR. JONES: Okay.

3 MR. COMBS: All right. Thank you, Nate.

4 Talk to you later.

5 MR. JONES: Safe travels.

6 (Deposition concluded at 2:40 p.m.)

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CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary will be made on the Errata Sheet.

Harry Johnson, M.D., FACOG, FACS

Date

(If needed, make additional copies of the Errata Sheet on the next page or use a blank piece of paper.)

ERRATA SHEET

Case: Ethicon, Inc.

Witness: Harry Johnson, Jr., M.D.

Date: March 21, 2017

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1 State of Maryland

2 County of Baltimore, to wit:

3 I, SUSAN M. WOOTTON, a Notary Public of the
4 State of Maryland, County of Baltimore, do hereby
5 certify that the within-named witness personally
6 appeared before me at the time and place herein set
7 out, and after having been duly sworn by me, according
8 to law, was examined by counsel.

9 I further certify that the examination was
10 recorded stenographically by me and this transcript is
11 a true record of the proceedings.

12 I further certify that I am not of counsel
13 to any of the parties, nor in any way interested in the
14 outcome of this action.

15 As witness my hand this 4th day of
16 April, 2017.

17  _____

18 Susan M. Wootton, RPR

19 Notary Public

20 My Commission Expires:

21 June 12, 2019